

REMARKS

Reconsideration is respectfully requested.

Claims 1-43 are pending. Claims 8-12, 14-16, 18-20, and 37-43 have been withdrawn by the Examiner as directed to a non-elected invention. Claims 44 and 45 have been added. Claims 1-7, 13, 17, and 21-36 are under examination by the Examiner to the extent to which they read on the elected species position 332. Amendment to and cancellation of the claims does not affect inventorship.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Claim Numbering

Applicants respectfully thank the Examiner for re-numbering mis-numbered claims 33-42. Applicants note and additional claim 42. Applicants have amended the second claim 42 as claim 43. The correct numbering of the claims is reflected in the listing of claims provided herein.

Priority

The Examiner states that Provisional U.S. Patent Application No. 60/414,443 does not provide adequate support under 35 U.S.C. § 112 for the limitation "position 332" in the Fc region.

Applicants respectfully traverse this observation of the Examiner. Because the Examiner does not cite any art with a critical date falling between the claimed priority date and the filing date of the instant application, this observation remains moot.

Applicants note that the present application was granted priority to Provisional Application Nos. 60/384,197 and 60/360,843 on April 12, 2006.

Specification

The Examiner instructs the Applicants to review and correct all spelling, trademark and like errors.

Applicants do not believe the specification contains any such errors. However, if the Examiner objects to a particular portion of the specification, Applicants will amend the specification as appropriate.

Claim Objections

The Examiner objects to claim 1 as having an additional "an" at the beginning of the claim. The Examiner also objects to claims 17 and 22-31 as reciting "CDC," and or "ADCP." The Examiner suggests amending the claims to recite the full names of CDC and ADCP.

Applicants have amended the first instance of CDC at claim 16 to recite “complement dependent cytotoxicity,” and have amended the first instance of ADCP to recite “antibody dependent cell-mediated cytotoxicity.”

The amendment merely makes explicit that which was implicit in the claims as filed. Applicants note that the present ground for objection is not a reason related to patentability under Title 35 of the United States Code.

Rejections under 35 U.S.C. §112, second paragraph

Claims 21-23, 28, and 33 stand rejected under 35 U.S.C. §112, second paragraph as indefinite for reciting “modulate” because the recitation of the term “modulate” is ambiguous.

Applicants respectfully traverse this ground for rejection. The term “modulate” modifies “effector function” in the rejected claims. Applicants submit that one of skill in the art would readily understand the term “modulate.”

However, without acquiescing to the propriety of the rejection, and solely to advance prosecution, the term “modulate” has been amended to recite “enhanced or reduced.” This amendment merely makes explicit that which was implicit in the claim, and does not constitute a narrowing amendment under Title 35 of the United States Code.

Support for the amendment may be found, for example, in paragraph [099], which refers to enhanced or reduced effector function. Paragraph [103] refers to enhancing or reducing effector function in the context of engineering glycoforms. Example 4, beginning at paragraph [217], discloses reduced effector function. Paragraph [211] refers to “improved effector function,” which is disclosed as binding more tightly to FcγRIIIa [211]. In this context, Applicants further note that “improved” effector function is synonymous with “enhanced” effector function.

Applicants respectfully request that this ground for rejection be withdrawn.

Rejections under 35 U.S.C. §112, first paragraph – Enablement

A. “Fc variant”

Claims 1-7, 13, 17, 21-33, and 36 stand rejected over the term “Fc variant.”

The Examiner states that the instant claims encompass in their breadth *any* variant Fc comprising at least one amino acid substitution. The Examiner states that “the specification does not appear to give guidance as to which residues should or should not be changed to preserve any particular function. Although the specification does provide working examples of antibodies with position 332 of the Fc region altered (e.g. see Figures 13a, 22a, 22b), the variation by the instant claim language is extensive.”

Without acquiescing to the propriety of the rejection, the claims have been amended to recite specific substitution positions within the Fc variant. In addition, the Examiner suggests that amending the claims to antibody and/or immunadhesin would obviate this ground for rejection. The Applicants respectfully draw the Examiner’s attention to new claims 44 and 45, which recite “antibody” and “Fc fusion”. For clarification, “fc fusions” are defined at paragraph [087] as

a protein wherein one or more polypeptides is operably linked to Fc. Fc fusion is herein meant to be synonymous with the terms "immunoadhesin", "Ig fusion", "Ig chimera", and "receptor globulin" (sometimes with dashes).

Accordingly, the Applicants submit that the specification fully enables the claimed invention and the rejection should be withdrawn.

B. "effector function"

The Examiner has rejected claim 21 over the term "effector function." The Examiner asserts that "the specification only discloses effector function as ...ADCC, ...CDC and ...ADCP," and proposes claim 22 as an example of acceptable wording.

Applicants respectfully traverse this ground for rejection. However, in the interests of furthering the prosecution of this case, and without acquiescing to the propriety of the rejection, the claims have been amended to recite "an effector function selected from the group consisting of ADCC, CDC, or ADCP." Applicants reserve the right to claims directed to "effector function" in future divisional and continuation applications.

This ground for rejection is now moot. Applicants respectfully request that this ground for rejection be withdrawn.

Rejections under 35 U.S.C. §112, first paragraph – written description

Claims 1-7, 13, 17, 21-33 and 36 stand rejected as failing to comply with the written description requirement. The Examiner states that "[t]here is insufficient written description in the specification as-filed of "Fc variant" as recited in the instant claims."

Applicants respectfully traverse this ground for rejection. However, in the interests of furthering the prosecution of this case, and without acquiescing to the propriety of the rejection, the claims have been amended to recite specific positions for amino acid substitutions. As such, the Applicants submit the written description is sufficient, and the rejection should be withdrawn.

Rejections under 35 U.S.C. §102(b)

Claims 1-7, 13, 17 and 21-36 stand rejected under 35 U.S.C. §102(b) as anticipated by Lazar et al. (WO 03/074679).

WO 03/074679 is not a prior art reference under 35 U.S.C. §102(b). 35 U.S.C. §102(b) requires that

the invention was patented or described in a printed publication ... more than one year prior to the date of application for patent.

In evaluating the priority claim of the present application, the Examiner states that "the priority application ... 10/379,392 upon which benefit is claimed appear[s] to provide adequate support under 35 U.S.C. 112." U.S. Patent Application No. 10/379,392, filed March 3, 2003, was filed before the publication date of WO 03/074679, and moreover has the same filing date as WO 03/074679. Applicants further note that the

present application claims priority to the same U.S. Provisional Application Nos. 60/384,197 and 60/360,843 as the cited WO 03/074679 reference. Applicants note that the present application was granted priority to Provisional Application Nos. 60/384,197 and 60/360,843 on April 12, 2006, before the April 14, 2006 mailing date of the present office action.

WO 03/074679 is therefore not a reference under 35 U.S.C. §102(b). Applicants respectfully request that this ground for rejection be withdrawn.

Rejections under 35 U.S.C. §103

Claims 1 and 36 stand rejected over Lazar et al. (WO 03/074679) in view of Lam et al. (U.S. Patent No. 6,171,586).

As noted above, WO 03/074679 is not a prior art reference under 35 U.S.C. §102(b). Because the instant application and the cited reference WO 03/074679 share a filing date and priority claims to U.S. Provisional Application Nos. 60/360,843 and 60/384,197, WO 03/074679 is not a prior art reference under 35 U.S.C. §§102(a) or 102(e). WO 03/074679 cannot be used in combination with another reference under 35 U.S.C. § 103.

Applicants respectfully request that this ground for rejection be withdrawn.

Double Patenting

The Examiner has provisionally rejected claims 1-7, 13, 17, and 21-36 on the ground of obviousness-type double patenting over claims 1-5, 7, 8, 10-28, 30-41, 43-53, 59 and 61 in U.S. Patent Application No. 10/672,280.

Because both the present case and U.S. Patent Application No. 10/672,280 are pending and subject to continued prosecution which may obviate any substantive ground for obvious-type double-patenting, Applicants respectfully request that the provisionally rejection be hold in abeyance until allowable subject matter has been found in the instant applications.

Conclusion

Applicants respectfully request a search of the additional non-elected species.

The present application is in condition for allowance. Early notification thereof is respectfully requested.

Although the Applicants do not believe any additional fees are required, the Commissioner is authorized to charge any additional fees, including extension fees or other relief, which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order 463077-00275; Docket No.: A-71386-8).

The Examiner is invited to contact the undersigned at (415) 781-1989 if any issues may be resolved in that manner.

Respectfully submitted,

DORSEY & WHITNEY LLP

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Customer Number: 32940

Dorsey & Whitney LLP

555 California Street, Suite 1000

San Francisco, CA 94104-1513

Telephone: (415) 781-1989

Facsimile: (415) 398-3249

By: Timothy A. Worrall

Timothy A. Worrall, Reg. No. 54,554 for
Robin M. Silva, Reg. No. 38,304